



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Encore Medical, L.P.
Ms. Teffany Hutto
Manager, Regulatory Affairs
9800 Metric Boulevard
Austin, Texas 78758

Re: K130048

Trade/Device Name: Reverse® Shoulder Prosthesis Monoblock
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, HSD
Dated: September 26, 2013
Received: September 27, 2013

Dear Ms. Hutto:

This letter corrects our substantially equivalent letter of October 29, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K130048

Device Name: Reverse Shoulder Prosthesis Monoblock

Indications for Use:

**Reverse® Shoulder Prosthesis Monoblock
Indications for Use**

The Reverse® Shoulder Prosthesis Monoblock is indicated for patients with a functional deltoid muscle with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint:

- In cases of fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder, including humeral head fracture or displaced 3- or 4-part fractures of proximal humerus. (For cemented implantation only)
- In cases of bone defect in proximal humerus.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s).

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented or cementless use.

Indications for RSP Humeral Stem Adapters:

The Reverse® Shoulder Prosthesis (RSP) is indicated for treatment of patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

During primary surgery, after the humerus is prepared for the RSP humeral stem (modular and monoblock), if purchase to the glenoid bone is insufficient to bear the load of the glenoid baseplate and alternative glenoid bone reconstruction and/or repair is inadequate, the corresponding RSP humeral stem adapter can be used to convert the RSP humeral stem to hemiarthroplasty prosthesis as a salvage procedure. During revision surgery of an RSP (modular or monoblock), if the glenoid bone stock appears to be insufficient to bear the load of the glenoid baseplate and alternative glenoid bone reconstruction and/or repair is inadequate, the corresponding RSP humeral stem adapter can be used to convert the RSP device to hemiarthroplasty prosthesis as a salvage procedure. For modular RSP stems, the Foundation Shoulder humeral head should be used. For the monoblock stem, the Turon humeral head should be used. This stem/adaptor construct is not approved for use as a surrogate for traditional hemiarthroplasty or anatomic replacement indications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



OCT 29 2013

510(k) Summary**Date:** October 28, 2013**Manufacturer:**

DJO Surgical (Legal Name: Encore Medical, L.P.)
 9800 Metric Blvd
 Austin, TX 78758

Contact Person:

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Product	Classification	Product Code
Reverse® Shoulder Prosthesis Monoblock Humeral Stem	Class II	KWS, HSD

Product Code	Regulation and Classification Name
KWS	Shoulder joint metal/polymer semi-constrained prosthesis per 21 CFR 888.3660
HSD	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis per CFR 888.3690

Description:

The RSP Monoblock system is designed so that the "ball" of the articulation fits into the glenoid baseplate, and the "cup" of the articulation fits into a metal cup that is joined to the humeral stem. The components included in this system are a glenoid head, a humeral socket joined with humeral stem, a glenoid baseplate, and baseplate screws.

The modification outlined in this application consists of an addition to the Indications for Use for the humeral stem to allow for cementless implantation. There is no change to the fundamental scientific technology of the RSP Monoblock with the modifications in this 510(k) submission. This includes no changes to materials, design, sterilization, packaging, or method of manufacture.

Indications for Use:

The Reverse® Shoulder Prosthesis Monoblock is indicated for patients with a functional deltoid muscle with a grossly deficient rotator cuff shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff shoulder joint:

- In cases of fracture of glenohumeral joint from trauma or pathologic conditions of the shoulder, including humeral head fracture or displaced 3- or 4-part fractures of proximal humerus. (For cemented implantation only)
- In cases of bone defect in proximal humerus.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s).

The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented or cementless use.

Indications for RSP Humeral Stem Adapters:

The Reverse® Shoulder Prosthesis (RSP) is indicated for treatment of patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

During primary surgery, after the humerus is prepared for the RSP humeral stem (modular and monoblock), if purchase to the glenoid bone is insufficient to bear the load of the glenoid baseplate and alternative glenoid bone reconstruction and/or repair is inadequate, the corresponding RSP humeral stem adapter can be used to convert the RSP humeral stem to hemiarthroplasty prosthesis as a salvage procedure. During revision surgery of an RSP (modular or monoblock), if the glenoid bone stock appears to be insufficient to bear the load of the

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glenoid baseplate and alternative glenoid bone reconstruction and/or repair is inadequate, the corresponding RSP humeral stem adapter can be used to convert the RSP device to hemiarthroplasty prosthesis as a salvage procedure. For modular RSP stems, the Foundation Shoulder humeral head should be used. For the monoblock stem, the Turon humeral head should be used. This stem/adapter construct is not approved for use as a surrogate for traditional hemiarthroplasty or anatomic replacement indications.

Predicate Devices: RSP Monoblock Humeral Stem, DJO Surgical, K100741
Zimmer Tribecular Metal Reverse Shoulder System, K122692
RSP Monoblock Hemi Adapter, K111735

Comparable Features to Predicate Device(s): Features comparable to predicate devices include the same material, indications, surgical implantation technique, and intended use.

Non-Clinical Testing: Labeling update only.

Clinical Testing: None provided.